

**REMARKS**

Claims 1-5, 9-14, 128 and 138-139 are currently pending to which the Examiner provides several rejections that are listed here in the order in which they are addressed.

- I. Claims 1-5, 9-14, 128 and 138 are rejected under 35 USC ¶ 112 § 1 as the specification allegedly fails to comply with the written description requirement.
- II. Claims 1-5, 9-14, 128 and 138-139 are allegedly obvious in view of Nathan.

The Examiner's rejection are responded to as follows

**I. The Claims Are Adequately Described By The Specification**

The Examiner makes a written description rejection, quoting MPEP 2163 as follows:

“A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

(See Office Action, page 5). There are at least three problems with this. First, the Examiner does not provide the full quote of the MPEP section; the full quote is as follows:

“The claimed invention as a whole may not be adequately described where an invention is described **solely** in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.”

(See MPEP 2163) (emphasis added). Clearly, when the sentence provided by the Examiner is read in the context of the full paragraph, it is clear the topic is really “inventions described solely in terms of how to make them.” This has no relevancy to the present claims, which provide specific sequence information on both sides of an insert.

The second problem with this cite is that it is referring to the facts of *Eli Lilly*. The Examiner is no doubt aware that the Federal Circuit has made NUMEROUS statements concerning the *Eli Lilly* case, out of a concern that it will be applied too restrictively. In Applicants’ prior response, two (more recent) cases were discussed and quoted, making it clear that there is no *per se* requirement for structure. The MPEP cite made by the Examiner does not reflect the current treatment of structure in claims.

The third problem is that, while the Examiner cannot “fix” or update the MPEP, the Examiner is REQUIRED to deal with EVERY argument made by Applicants. Thus, it is respectfully submitted that the Examiner is required to respond to Applicants’ arguments based on the *Capon* and *Falkner* cases (even if the outdated MPEP does not). Unfortunately, a review of the Office Action finds no reference whatsoever to these cases.

Nonetheless, Applicants are mindful of the need to expedite the prosecution. In this regard, the Examiner makes note of sequence information in Figure 19. Without acquiescing to the Examiner’s position or waiving the above-made arguments, and hereby preserving the right to prosecute the unamended (or similar) claims in the future, the claims have been amended to specify particular sequences for N50 set forth in Figure 19.

As a result, the Applicants respectfully request that the Examiner withdraw the present objections.

## **II. The Claims Are Not Obvious**

The Examiner argues that the claims are obvious, citing the Nathan reference. The Examiner must notice, however, that Nathan does not disclose any constructs that are regulated by peptide or protein effectors. While the Examiner points to a shopping list of possible effectors in the Nathan reference, the Examiner must also acknowledge that what one might seek or desire is not determinative of obviousness. Indeed, the Supreme Court in the *Graham* case made it clear that lack of obviousness can be shown by demonstrating a long-felt – but unmet – need. Said another way, it is the person who succeeds that is awarded a patent. See *Washburn*, 143 U.S. 275, 282-283 (1892) (“... .

courts have not been reluctant to sustain a patent to the man who has taken the final step which has turned a failure into a success.”).

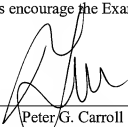
Moreover, the claims have been amended for other reasons (see above) to specify particular sequences associated with peptide and protein effectors. Such sequences are not found in the Nathan reference. As such the obviousness rejection cannot stand.

### CONCLUSION

The Applicants believe that the arguments set forth above traverse the Examiner's rejections and, therefore, request that all grounds for rejection be withdrawn for the reasons set above. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned collect at 617.984.0616.

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By: \_\_\_\_\_

  
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